CHARTERED
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CANADA MEDICINES LAW, CONTROLLED DRUG REGULATIONS & PRESCRIBING COMPLIANCE

Fully Accredited By:

Chartered Institute of Professional Certifications

CPD Certification Service

PROGRAM OVERVIEW

Canada's medicines regulatory landscape has never been more demanding. Health Canada now oversees more than 25,000 marketed pharmaceutical products and processes thousands of adverse drug reaction reports each year. As enforcement expectations intensify across prescribing, pharmacovigilance, and controlled-drug management, healthcare organizations face escalating compliance complexity and serious legal exposure — making strong medicines governance and prescribing oversight more critical to your professional and institutional survival than ever before.

This certified program is designed to equip you with a practical and authoritative command of Canada's medicines law and prescribing compliance framework. You will gain critical insight into the regulatory structure governing medicines, controlled drugs, and prescribing practices across Canada, with in-depth examination of key legislation including the **Food and Drugs Act, Food and Drug Regulations, Controlled Drugs and Substances Act, Narcotic Control Regulations, and Benzodiazepines and Other Targeted Substances Regulations**. With this stronger foundation, you will be far better positioned to navigate complex compliance obligations, strengthen prescribing governance, and lead safer healthcare practices within your organization.

Throughout the program, you will sharpen your ability to interpret prescribing authority, scope of practice requirements, and professional accountability obligations with confidence and precision. You will also develop practical expertise in **clinical documentation, opioid stewardship, and adverse drug reaction**

ACCREDITATIONS

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PROGRAM OVERVIEW

reporting — capabilities that directly improve patient safety while reducing regulatory exposure. The program will further strengthen your **compliance monitoring and governance controls**, helping you identify compliance vulnerabilities before they escalate into legal issues. Critically, you will learn how to prepare effectively for **audits, inspections, and regulatory investigations**, equipping your organization to minimize enforcement risks and respond decisively when scrutiny arrives.

Through realistic case studies and scenario-based discussions, you will gain proven strategies to assess **regulatory risks and respond with confidence in even the most complex compliance situations**. The program also addresses the emerging challenges in digital prescribing and telemedicine — keeping you ahead of evolving regulatory expectations in Canada's rapidly transforming healthcare environment.

Upon successful completion of the program, you will attain the **Certification of Canada Medicines Law and Prescribing Compliance**, an industry-recognized credential that validates your expertise in navigating complex medicines regulations, strengthening prescribing compliance, and leading effective healthcare governance within Canada's evolving regulatory landscape.

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KEY SKILLS YOU WILL GAIN

From This Program

FOOD AND DRUGS ACT INTERPRETATION
CONTROLLED DRUGS AND SUBSTANCES ACT (CDSA) COMPLIANCE
NARCOTIC CONTROL REGULATIONS COMPLIANCE

TARGETED SUBSTANCES REGULATIONS MANAGEMENT
PRESCRIBING COMPLIANCE GOVERNANCE
MEDICINES REGULATORY INTERPRETATION

CONTROLLED-DRUG RISK MANAGEMENT
HEALTHCARE COMPLIANCE AUDITING
REGULATORY INSPECTION READINESS
PRESCRIBING DOCUMENTATION DEFENSIBILITY

CLINICAL DOCUMENTATION STANDARDS
OPIOID STEWARDSHIP GOVERNANCE
PRESCRIPTION MONITORING ANALYSIS
ADVERSE DRUG REACTION REPORTING
PHARMACOVIGILANCE COMPLIANCE

HEALTHCARE GOVERNANCE FRAMEWORKS
SCOPE OF PRACTICE COMPLIANCE

YOUR FACULTY DIRECTOR

Scott Sawler

Highly Distinguished Healthcare Regulatory Affair Expert and Former Director General (DG) of Health Canada's Marketed Health Products Directorate (MHPD)

Scott Sawler is one of Canada's most respected authorities on medicines regulation and healthcare compliance, with over 30 years of distinguished experience across Health Canada, pharmaceutical regulation, clinical trials, and controlled-drug governance. He currently serves as **President of Canadian Regulatory Affairs at the Drug Safety Institute** and previously held senior leadership roles at Health Canada, including **Director General of the Marketed Health Products Directorate (MHPD) and the Natural and Non-prescription Health Products Directorate (NNHPD)**.

Scott has led major regulatory and policy initiatives spanning medicines governance, prescribing compliance, post-market surveillance, and controlled-drug oversight. He played a **key role in developing Health Canada's regulatory frameworks for marketed health products and pharmaceutical brand-name review**, while overseeing risk-benefit assessments and regulatory compliance strategies. His expertise spans clinical trial regulation, narcotic distribution controls, pharmacovigilance, pharmacy operations, and healthcare compliance governance. Scott has also **advised pharmaceutical companies, healthcare organizations, and regulatory stakeholders on complex prescribing, regulatory, and medicines safety matters** across Canada's highly regulated healthcare environment — bringing rare insider-level perspective directly to every participant.

OUR PARTICIPANTS

Over 70% of FORTUNE 500 Companies Have Attended Our Accredited Programs Before

PROGRAM AGENDA

MODULE 1 - CANADA MEDICINES REGULATORY FRAMEWORK AND GOVERNANCE

- Overview of Canada's Medicines Regulatory Framework and Governance Landscape
- Key Institutions, Legal Authorities, and Accountability Structures.
- How Medicines Law Intersects With Healthcare Delivery, Prescribing, and Compliance.

MODULE 2 - FOOD AND DRUGS ACT: LEGAL FOUNDATIONS OF MEDICINES COMPLIANCE

- Food & Drugs Act and Food & Drug Regulations
- Core Legal Principles Affecting Medicines Regulation and Compliance
- Practical Interpretation of Statutory and Regulatory Obligations

MODULE 3 - DRUG AUTHORIZATION, LICENSING AND POST-MARKET REGULATORY OBLIGATIONS

- Drug Approval Pathways and Market Authorization Concepts
- Establishment Licensing and Operational Regulatory Obligations
- Post-authorization Responsibilities and Compliance Implications

MODULE 4 - CONTROLLED DRUGS AND SUBSTANCES ACT (CDSA): COMPLIANCE AND ENFORCEMENT

- Controlled Drugs and Substances Act Foundations
- Purpose, Structure, and Legal Consequences of Non-compliance.
- Practical Implications for Organizations Handling Controlled Substances

MODULE 5 - NARCOTICS, BENZODIAZEPINES AND TARGETED SUBSTANCES REGULATIONS

- Narcotic Control Regulations
- Benzodiazepines and Other Targeted Substances Regulations
- Key Operational Expectations for Storage, Record-keeping, Prescribing, and Accountability.

MODULE 6 - PRESCRIBING AUTHORITY, SCOPE OF PRACTICE AND PROFESSIONAL ACCOUNTABILITY

- Prescribing Authority and Scope of Practice
- Professional Accountability Across Physicians, Nurse Practitioners, Pharmacists, and Institutions.
- Limits of Authority, Delegation, and Governance Oversight.

PROGRAM AGENDA

MODULE 7 - SAFE PRESCRIBING PRACTICES, DOCUMENTATION AND RISK MANAGEMENT

- Safe Prescribing Standards and Clinical Documentation
- Documentation Failures, Defensibility, and Risk Management.
- Practical Controls to Support Compliant Prescribing Decisions

MODULE 8 - OPIOID STEWARDSHIP, PRESCRIPTION MONITORING AND MISUSE PREVENTION

- Opioid Stewardship and Misuse Prevention
- Prescription Monitoring Programs and Risk Indicators
- Governance Responses to Problematic Prescribing Patterns

MODULE 9 - PHARMACOVIGILANCE, ADVERSE DRUG REACTION REPORTING AND PATIENT SAFETY

- Pharmacovigilance and Adverse Drug Reaction Reporting
- Internal Escalation and Reporting Responsibilities
- Using Safety Information to Improve Compliance and Patient Protection

MODULE 10 - MEDICINES COMPLIANCE SYSTEMS, AUDITS AND REGULATORY INVESTIGATIONS

- Compliance Systems, Internal Controls, and Governance Frameworks.
- Audits, Inspections, and Regulatory Investigations.
- Preparing Organizations and Professionals for Regulatory Scrutiny

MODULE 11 - PROFESSIONAL DISCIPLINE, LIABILITY EXPOSURE AND ENFORCEMENT RISKS

- Professional Discipline and Liability Exposure
- Enforcement Actions and Regulatory Consequences
- Managing Organizational and Individual Accountability Risk

MODULE 12 - DIGITAL PRESCRIBING, TELEMEDICINE AND EMERGING COMPLIANCE CHALLENGES

- Emerging Issues in Digital Prescribing and Telemedicine
- Controlled Medicines Governance in Technology-enabled Care Models
- Forward-looking Compliance and Policy Challenges

YOUR CHARTER DESIGNATION

Chartered Institute of Professional Certifications' programs are unique as they provide you with professional charter designations and marks that can be used across your lifetime once you have completed our programs.

Upon successfully completing this program, you will earn the **Certification of Canada Medicines Law and Prescribing Compliance**, an industry-recognized certification with lifelong validity. This prestigious credential validates your authority to interpret and apply Canada's medicines and controlled-drug regulations, strengthen prescribing compliance practices, and lead effective medicines governance within Canada's highly regulated healthcare environment. It further elevates your professional credibility and showcases your expertise in compliance and audit readiness, prescribing risk management, and controlled-drug governance.

This program is developed by the **Chartered Institute of Professional Certifications** and the content of this program has been certified by **CPD Certification Service** as conforming to continuing professional principles.

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We Collaborate With Instructors From Renowned Institutions

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London Business School

CONTACT US TODAY

We Thank You for Your Ongoing Support of Our Programs

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